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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,492	02/26/2004	Ramez Emile Necola Shehada	64693-094	7995

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EXAMINER	
TOTH, KAREN E	

ART UNIT	PAPER NUMBER
3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

HH

Office Action Summary	Application No.	Applicant(s)	
	10/789,492	NECOLA SHEHADA ET AL.	
	Examiner	Art Unit	
	Karen E. Toth	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after t he mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1,5,15-27,62,68,70,75 and 76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *62,68 and 70* is/are allowed.

6)☒ Claim(s) *1,5,15-27 and 76* is/are rejected.

7)☒ Claim(s) *75* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

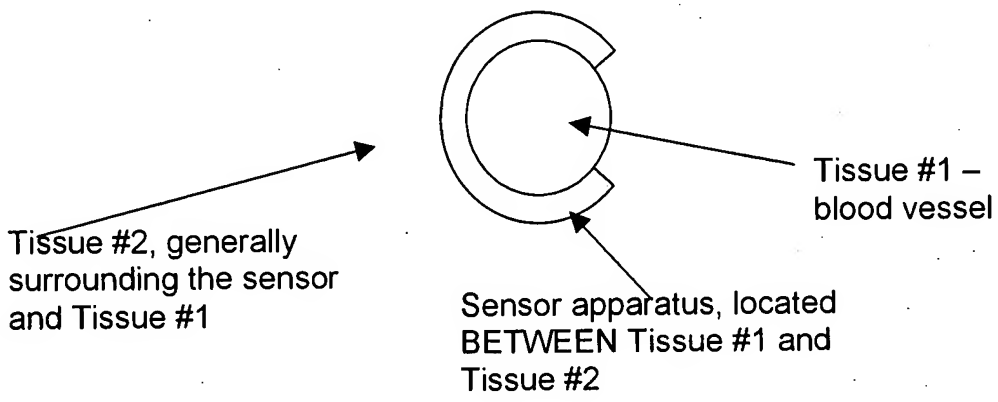
Response to Arguments

1. Applicant's arguments filed 11 July 2007 have been fully considered but they are not persuasive.

2. Applicant argues that Miesel (US Patent 6106477) does not disclose a sensor configured to be implanted against and between a first tissue and a second different tissue. The Examiner disagrees; the phrase "configured to be placed between two tissues" is an intended use limitation and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Miesel may be implanted such that one side contacts a first tissue (a blood vessel) and another side surrounds a different tissue (the tissue surrounding the blood vessel in the patient's body).

Applicant also argues that Miesel's second sensor is not in contact with the blood vessel – this is true, since the second sensor is used to measure a property of the second tissue, and therefore has no need to contact the first tissue, the blood vessel. Applicant argues that, since Miesel's second sensor measures ambient pressure, it is not measuring a tissue property. Since it is measuring a property of the tissue surrounding the blood vessel, such tissue would be the ambient environment, and an ambient pressure would be a property of the surrounding, second, tissue.

Applicant again argues that Miesel cannot be between two different tissues. Examiner still disagrees – in addition to the reasoning presented above, please see the following figure:



Applicant appears to be have misunderstood Examiner's phrasing; in the rejection of claim 1, the statement "a first sensor for sensing a physiological tissue property proximate to the first surface; a second sensor for sensing the same physiological tissue property proximate to the second surface" is stating that the sensors are sensing the same physiological property of a tissue. The location of the sensors as being configured to sense two different tissues is already set forth earlier in the rejection, and this statement merely clarifies that both sensors are sensing the same type of property of tissue.

It is not clear why Applicant argues that the cited passage "does not even suggest sensing of the same tissue by the second sensor from the second surface", since Examiner has not attempted to cite such a step, nor has applicant claimed such a limitation.

Applicant further alleges that Miesel does not measure the difference between a same property measured from a first tissue and a second tissue by two different sensors. Miesel uses two separate sensors to take two pressure measurements of two tissues, and determines the pressure differential between the two measurements. Applicant also has chosen to use the example of oxygenation to illustrate the necessity for differential measurements. Examiner must point out that measuring oxygenation is found in a dependent claim, and therefore does not factor into the suitability of Miesel for rejecting claim 1.

Claim Rejections - 35 USC § 102

3. Claims 1, 15, 18, 21, 23, 27 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Miesel.

Regarding Claim 1, Miesel discloses a system comprising an implantable housing (element 10) including a first surface (element 15) and a second surface (element 11) both on the outside of the housing (column 5, lines 43-45); a first sensor for sensing a physiological tissue property proximate to the first surface (column 5, lines 54-55); a second sensor for sensing the same physiological tissue property proximate to the second surface (column 5, lines 3-7); and a processing system in communication with both sensors for computing a difference between the results of the physiological tissue property measurements (column 5, lines 5-7; column 7, lines 28-35 and 39-40), where the sensing surfaces may be on substantially opposite sides of the device (Figure

1). The system may be implanted such that the first sensor rests against a first tissue and the second sensor rests against a second tissue.

Regarding Claim 15, the device of Miesel may be used to deliver energy to the tissue proximate to the sensing surfaces, since oxygenation sensing (column 5, lines 19-21) comprises transmission of light.

Regarding Claim 18, Miesel further discloses that the implantable device comprises a power source, electronics, and communications circuits (element 57; Figure 12).

Regarding Claim 21, Miesel further discloses that the device may include an antenna for transmitting signals (column 11, lines 55-57).

Regarding Claim 23, Miesel further discloses that the physiological tissue property being sensed may be temperature (column 5, lines 13-14); and that the system may be configured to calculate the difference between the first and second sensors (column 10, lines 31-40).

Regarding Claim 27, Miesel further discloses that the device may comprise anchors (element 95; column 7, lines 13-17).

Claim Rejections - 35 USC § 103

4. Claims 5, 16, 17, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miesel in view of Sun (US Patent 6122536).

Regarding claim 5, Miesel discloses all the elements of the disclosed invention, as described above, except for the system being used to sense oxygenation. Miesel

further discloses that the sensors disclosed in the preferred embodiment may be supplemented by or replaced by alternate sensors, such as those capable of sensing oximetry or partial pressure of oxygen (column 5, lines 10-13 and 19-22). Sun teaches a similar implantable sensing system that may be used to sense oxygenation (column 1, lines 15-17), since it is well known in the art to use an implantable sensor to monitor tissue oxygenation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Miesel with sensors for sensing oxygenation, as taught by Sun, since it is well known in the art to use implantable sensors to monitor tissue oxygenation.

Regarding claim 16, Miesel discloses all the elements of the disclosed invention, as described above, except for the system comprising a third sensing system configured to sense a physiological property of tissue proximate to the housing that is different from the property sensed by the first two sensors. Sun teaches an implantable sensing system comprising a plurality of sensors, where one sensor may be configured to sense a physiological property of tissue proximate to the system different that a physical property sensed by the other sensors (column 11, lines 14-21), in order to provide a more complete view of a patient's condition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Miesel with a third sensor configured to sense a different tissue property, as taught by Sun, in order to provide a more complete view of the patient's condition.

Regarding claim 17, Miesel discloses all the elements of the disclosed invention, as described above, except for the sensing systems being located behind optically

transparent material. Sun teaches an implantable sensing system with similar sensors that are located behind optically transparent material (elements 46, 48, 50; column 11, lines 14-15 and 17-19), in order to protect the sensors while still allowing accurate sensing to occur. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Miesel with the sensors behind optically transparent material, as taught by Sun, in order to protect the sensors while still allowing accurate sensing.

Regarding claim 26, Miesel disclose all the elements of the current invention, as described above, except for the sensing systems including optical fibers. Sun teaches an implantable sensing system using optical fibers to connect to a plurality of sensors (column 11, lines 54-56), in order to provide accurate signal transmission. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Miesel with optical fibers, as taught by Sun, to provide accurate signal transmission.

5. Claims 20, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miesel in view of Gord (US Patent 5999848).

Regarding Claim 20, Miesel discloses all the elements of the current invention, as applied to Claim 1, except for the system including an antenna for receiving power.

Gord further teaches that the device may receive power signals (column 5, lines 34-36) in order to provide power for operation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Miesel with the power receiving capability of Gord, in order to provide power for operation.

Regarding Claim 22, Miesel discloses all the elements of the current invention, as applied to Claim 1, except for the system including an antenna for receiving signals.

Gord further teaches that the device may receive signals (column 5, lines 34-36) in order to control or modify operation of the device.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Miesel with the signal receiving capability of Gord, in order to control or modify operation of the system.

6. Claims 19, 24, 25, 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miesel in view of Hines (US Patent 6582365).

Regarding Claim 19, Miesel discloses all the elements of the current invention, as applied to Claim 1, except for the processing system being located outside the patient. Hines further teaches that the system includes a signal processing system (column 2, lines 52-54) that is located outside a patient (Figure 1), so that gathered data may be stored and processed for future reference. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Miesel with an external signal processing system, as taught by Hines, so that gathered data may be stored and processed for future reference.

Regarding Claim 24, Miesel discloses all the elements of the current invention, as applied to Claim 1, except for the system including a display configured to show information gathered by the sensing systems. Hines further teaches that the system includes a display that is used to show the gathered physiological data (column 2, lines 52-54), in order to allow medical professionals to examine the results of the gathered physiological data. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Miesel with the display of Hines, in order to allow medical professionals to examine the results of the gathered physiological data.

Regarding Claim 25, Miesel discloses all the elements of the current invention, as applied to Claim 1, except for the system including a display configured to show data corresponding to the difference between the signals gathered from the two sensing systems. Miesel further discloses that the system may be configured to calculate the difference between the first and second sensors (column 10, lines 31-40). Hines teaches that the system includes a display that is used to show gathered physiological data (column 2, lines 52-54), in order to give an indication of a patient's condition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Miesel with the display of Hines used to show data corresponding to the difference between the signals gathered by the sensing systems, in order to give an indication of a patient's condition.

Allowable Subject Matter

7. The following is a statement of reasons for the indication of allowable subject matter:

The prior art of record fails to anticipate or make obvious the methods of claims 62, 68, and 70, including, *inter-alia*, positioning an icon on a display to show the position of a sensing device within a body when receiving information from a device having two sensing systems.

8. Claim 75 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the structure of claim 75, including, *inter-alia*, including a display that is configured to depict an icon representing a device on the display relative to a depiction of the tissue to indicate the position of a device within a body when sensing using an implantable sensor having two sensing systems.

Conclusion

9. This is a request for continued examination. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action

in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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